and has caused at least one outbreak in Australia. Pink salmon, redfish, yellowtail, marlin, and amberjack have also been implicated in scombroid poisoning outbreaks that have occurred in the United States. Outside the United States, pilchards, herring, anchovies, bluefish, and sardines have been involved in a number of cases. Sardines and pilchards have become a major source of histamine poisoning in Great Britain. Japan had an outbreak associated with black marlin, and anchovies have been implicated in single incidents in Japan, the United States, and Great Britain (Ref. 9).

From 1977 to 1981 there were 68 outbreaks of scombroid poisoning involving 461 illnesses (Ref. 10). In March 1980, the Centers for Disease Control and Prevention reported that mahi-mahi accounted for 40 percent of the scombroid poisoning outbreaks reported in the United States. Since 1980, FDA has placed most shipments of mahi-mahi offered for entry into the United States on automatic detention because of the frequent occurrence of histamine levels exceeding 500 ppm (Ref. 11).

Histamine is a poisonous or deleterious substance under section 402 (a)(1) of the act because, when ingested at sufficiently high levels, it is known to cause scombroid poisoning (Ref. 12). In the September 14, 1982, notice, the agency established, on an interim basis, an AL of 500 ppm histamine in canned tuna (47 FR 40487). At this level, the agency considers histamine to present a hazard to public health. The agency is not changing the 500 ppm AL at this time because the threshold toxic dose of histamine is not known. However, the action level for canned tuna of 500 ppm will also apply to other species of raw, frozen, and canned fish, such as mahi-mahi, bluefish, amberjack, and mackerel, all fish that have been implicated in histamine poisoning outbreaks. Furthermore, the presence of other amine decomposition products in fish may have a synergistic effect on histamine toxicity. This synergism may dramatically lower the threshold toxic dose (Refs. 9 and 10).

Therefore, FDA is revising its histamine policy and announcing the availability of revised CPG 7108.24 ''Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species,'' which: (1) Includes a lower histamine DAL for decomposition, 50 ppm histamine rather than 100 ppm; (2) extends the application of the DAL of 50 ppm (5 mg per 100g) histamine for decomposition to raw and frozen tuna and mahi-mahi; (3) eliminates the provision that findings of less than 200 ppm histamine need to be confirmed by organoleptic evaluation; (4) states that, on a case by case basis, histamine levels equal to or greater than 50 ppm, but less than 500 ppm, may be used as evidence of decomposition in other species commonly implicated in instances of histamine poisoning when supported by other scientific data; and (5) states that the AL of 500 ppm histamine now applies to other species of fish that have been implicated in histamine poisoning outbreaks.

Title of Revised CPG 7108.24

The title of CPG 7108.24 ''Decomposition and Histamine in Canned Albacore, Skipjack, and Yellowfin Tuna'' has been changed to ''Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species'' to more accurately describe the contents of the revised CPG.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Eitenmiller, R. R., and S. C. DeSouza, ''Enzymatic Mechanisms for Amine Formation in Fish,'' in *Seafood Toxins*, edited by E. P. Ragelis, American Chemical Society, Washington, DC, pp. 431–442, 1984.

2. Behling, A. R., and S. L. Taylor , ''Bacterial Histamine Production as a Function of Temperature and Time of Incubation,'' *Journal of Food Science* 47:1311–1314, and 1317, 1982.

3. Memorandum from Division of Science and Applied Technology (HFS–425) to Division of Programs and Enforcement Policy (HFS–415), CFSAN, FDA, dated August 6, 1992.

4. Baranowski, J. D., H. A. Frank, P. A. Brust, M. Chongsiriwatana, and R. J. Premaratne, ''Decomposition and Histamine Content in Mahi-Mahi (*Coryphaena Hippurus*),'' *Journal of Food Protection* 53:217–222, 1990.

5. Frank, H. A., D. H. Yoshinaga, and W–K. Nip, ''Histamine Formation and Honeycombing During Decomposition of Skipjack Tuna, *Katsuwonus pelamis*, at Elevated Temperatures,'' *Marine Fisheries Review* 43:9–14, 1981.

6. Frank, H. A., and Yoshinaga, ''Histamine Formation in Tuna'' in *Seafood Toxins*, edited by E.P. Ragelis, American Chemical Society, Washington, DC, pp. 443–451, 1984.

7. Staruszkiewicz, W. F., ''Fluorometric determination of Histamine in Tuna: Collaborative Study'' in *Journal of the Association of Official Analytical Chemists* 60 (5) pp. 1131–1136, 1977.

8. Rogers, P. R., and W. F. Staruszkiewicz, ''Modification of GLC Method for Putrescine and Cadaverine and the Fluorometric Method for Histamine,'' Laboratory Information Bulletin no. 3794, July 1993.

9. Stratton, J. E., and S. L. Taylor, ''Scombroid Poisoning,'' in *Microbiology of Marine Food Products*, edited by Ward, D. R., and C. Hackney, Van Nostrand Reinhold, New York, pp. 333–344, 1991.

10. Taylor, S. L., ''Marine Toxins of Microbial Origin,'' *Food Technology* 42(3):94–98, 1988.

11. Regulatory Procedure Manual, part 9, Imports, Import Alert 16–05—''Automatic Detention of Mahi-Mahi Because of Histamine and Decomposition,'' August 14, 1991.

12. Taylor, S. L., J. Y. Hui, and D. E. Lyons, ''Toxicology of Scombroid Poisoning,'' in *Seafood Toxins*, edited by E. P. Ragelis, American Chemical Society, Symposium Series, no. 262, pp. 417–430, 1984.

Interested persons may, on or before September 5, 1995, submit to the Dockets Management Branch (address above) written comments on the revised CPG 7108.24. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The revised CPG 7108.24 and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 26, 1995.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 95–19059 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0238]

Drug Export; Benoquin (Monobenzone U.S.P) Cream 20%

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that ICN Pharmaceuticals, Inc., has filed an application requesting approval for the export of the human drug Benoquin (Monobenzone U.S.P) Cream 20% to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug

Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that ICN Pharmaceuticals, Inc., 3300 Hyland Ave., Costa Mesa, CA 92626, has filed an application requesting approval for the export of the human drug Benoquin (Monobenzone U.S.P) Cream 20% to Canada. This product is used for the final depigmentation in extensive vitiligo. The application was received and filed in the Center for Drug Evaluation and Research on June 15, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by August 14, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: July 21, 1995.

Betty L. Jones,

Acting Director, Office of Compliance, Center for Drug Evaluaiton and Research.

[FR Doc. 95–19153 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

[Docket No. 95D–0162]

Marketing of Condom-like Products: Policy Statement; Notice of Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is making generally available a policy statement issued on February 23, 1994, directly to manufacturers, distributors, and importers of condom products, regarding the marketing of condom-like products. The policy statement is intended to inform manufacturers, distributors, and importers of condoms and condom-like products, including those products labeled or packaged as novelty items, that such products are subject to all of the regulatory requirements for medical devices. This policy statement revises and supersedes the 1989 policy statement regarding the labeling of condoms. FDA is making the policy statement generally available at this time to help ensure that the policy is known and understood by the regulated industry and the public.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the policy statement to the Division of Small Manufacturers Assistance (HFZ–220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6597 (1–800–638–2041 outside MD). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the policy statement to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the policy statement and received comments are available for pubic examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765, ext. 157.

SUPPLEMENTARY INFORMATION: On February 13, 1989, FDA issued a statement of policy regarding the marketing of condoms. This policy statement was forwarded via certified mail—return receipt requested—to all manufacturers, importers, and repackagers of condoms for contraception or sexually transmitted disease prevention. Subsequently, FDA discovered that some marketers of functional condom-like products may have misinterpreted the 1989 policy statement, and were marketing functional condoms as novelty items without complying with condom leak testing requirements, current good manufacturing practice (CGMP) regulations, manufacturer registration, product listing, and premarket notification and clearance requirements. Such marketing is in violation of the Federal Food, Drug, and Cosmetic Act (the act) and implementing regulations. Therefore, to clarify that such products may only be legally marketed in compliance with these requirements, FDA issued a new policy statement on February 23, 1994.

Products that are capable of covering the penis with a closely fitting membrane and otherwise have the appearance of a condom are considered to be medical devices, regardless of their packaging or labeling. As such, these products must comply with all the above-referenced requirements. However, when condom-like products cannot be used as condoms, they need not meet the above requirements. For example, a product that resembles a condom but which has the closed end removed, the sides shredded, or the roll permanently sealed so that it is incapable of being unrolled would not be subject to the requirements of the act and the regulations. FDA emphasizes that merely labeling the products as a novelty does not remove it from the scope of the act or in any way exempt it from the requirements applicable to condoms.

Copies of this final policy statement, along with previous policy statements, are available for public examination in the Dockets Management Branch (address above).

Interested persons may, at any time, submit written comments on the final policy statement to the Dockets Management Branch (address above). Such comments will be considered when determining whether to amend the current policy statement. Two copies of any comments are to be